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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/479,608	01/06/2000	Radoje Drmanac	28110/35918	3272

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EXAMINER	
CLOW, LORI A	

ART UNIT	PAPER NUMBER
1631	

DATE MAILED: 11/05/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/479,608	DRMANAC ET AL.	
	Examiner	Art Unit	
	Lori A. Clow, Ph.D.	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondenc address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 July 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-35* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-35* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Applicants' arguments, filed 25 July 2003, have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claims 1-35 are currently pending. Claims 36-41 have been cancelled.

Information Disclosure Statement

It is noted that there are several applications pending at The United States Patent and Trademark Office from the instant inventor. Applicant is reminded of the duty to disclose information under 37 CFR § 1.56. See double patenting rejection below.

37 CFR § 1.56 Duty to disclose information material to patentability.(a) A patent by its very nature is affected with a public interest. The public interest is best served, and the most effective patent examination occurs when, at the time an application is being examined, the Office is aware of and evaluates the teachings of all information material to patentability. Each individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the Office, which includes a duty to disclose to the Office all information known to that individual to be material to patentability as defined in this section. The duty to disclose information exists with respect to each pending claim until the claim is cancelled or withdrawn from consideration, or the application becomes abandoned. Information material to the patentability of a claim that is cancelled or withdrawn from consideration need not be submitted if the information is not material to the patentability of any claim remaining under consideration in the application. There is no duty to submit information which is not material to the patentability of any existing claim. The duty to disclose all information known to be material to patentability is deemed to be satisfied if all information known to be material to patentability of any claim issued in a patent was cited by the Office or submitted to the Office in the manner prescribed by § 1.97(b)-(d) and 1.98. However, no patent will be granted on an application in connection with which fraud on the Office was practiced or attempted or the duty of disclosure was violated through bad faith or intentional misconduct. The Office encourages applicants to carefully examine:
(1) Prior art cited in search reports of a foreign patent office in a counterpart application, and
(2) The closest information over which individuals associated with the filing or prosecution of a patent application believe any pending claim patentably defines, to make sure that any material information contained therein is disclosed to the Office.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 13, and 20 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 9, and 32 respectively of U.S. Patent No. 6,537,755. Although the conflicting claims are not identical, they are not patentably distinct from each other because both methods involve detecting or identifying sequences of target nucleic acids comprising contacting a target nucleic acid with one or mixtures of a plurality if oligonucleotide probe molecules.

Claim 1 of US 6,537,755 recites a method of detecting a sequence of target nucleic acids comprising contacting a target nucleic acid (not attached to a support) with mixtures of probe molecules, detecting hybridization levels and identifying sequences by compiling overlapping sequences. Claim 1 of the instant application encompasses both nucleic acids which are attached to a support and those which are not attached to a support and therefore is obvious over claim 1 of '755.

Claim 9 of US 6,537,755 limits probes to be associated with identification tags. Claim 13 of the instant application requires that the probe be labeled. It would have been obvious to one of ordinary skill in the art that identification tags equate to labels and vice versa.

Finally, claim 20 of the instant application recites the limitation "removing false positives", not present in claim 32 of '755. However, it would have been obvious to one of ordinary skill in the art to include a step of eliminating false positives in the method of '755 where the motivation would have been to attain a high degree of accuracy in the method.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,537,755 B1.

Claim 1 requires identifying one or more sequences of a target nucleic acid comprising contacting a target with a first set of pools of probes, detecting a subset of pools for which a level of hybridization indicates a complementary probe, and identifying sequences of the target nucleic acid form a subset of pools by compiling overlapping sequences. US 6,537,755 (from

hereon '755) teaches detecting a sequence of a target nucleic acid comprising the same steps: (a) contacting a target nucleic acid with one or mixtures (or pools) of probes wherein the probes comprise different information regions (b) detecting probe molecules that hybridize, and (c) detecting a sequence of the target nucleic acid by overlapping sequences (column 2, lines 52-67; column 3, lines 1-27; column 4, lines 8-11).

Claim 2-4, 22, 23, 25, 32, 33 of the instant application comprises a method for identifying one or more sequences of target nucleic acid by contacting a target nucleic acid, assigning a hybridization score to each probe, and identifying sequences. '755 teaches a method to score probes using statistics which is taught at column 10, lines 1-16.

Claims 5-11 and 23 require that an additional pool be contacted in accordance with claim 1. '755 teaches that subsets of pools may be further divided at column 16, lines 66-67 and column 17, lines 1-17; column 15, lines 11-14.

Claim 12 requires that the target of claim 1 be labeled. '755 teaches labeled targets at column 3, lines 41-45.

Claims 13-16, 26, 27, 28, and 29 require that the probe of claim 1 be labeled. '755 teaches labeled probes column 12, lines 54-63; column 15, lines 61-67.

Claims 17-19, 30, and 31 require the pools to be immobilized on a solid support (array) which is taught at column 10, lines 21-33 of '755.

Claims 20, 21, 22, 34, and 35 require contacting a target nucleic acid, as in claim 1, covalently joining adjacently hybridized probes, detecting a subset of pools, and identifying sequences from the subset of covalently joined pools by overlapping sequences. '755 teaches the same steps at column 4, lines 1-29.

The step of eliminating probes with false high scores by analysis of overlapping sequences or analysis of hybridization scores pertaining to all claims is not specifically taught as an exact step of the said methods. However, '755 does teach that subsets of pools are selected from negative probes and analyzed by a reader that detects and discriminates individual molecules. For a given target, most of the probes will be negative and some will be positive. A positive probe subset is chosen (column 9, lines 25-34). It would have been obvious to include a step of eliminating false positives where the motivation would have been to attain a high degree of accuracy in the method.

While the steps of the method in '755 are not taught in the identical sequence as recited in the instant claims, it would have been prima facie obvious to combine the various steps of the preferred embodiments in order to practice the claimed invention. '755 motivates one to do so by stating that the practice of the procedures of the invention may be employed to obtain any desired level of sequence, from pattern hybridization to overlapping or non-overlapping probes up through assembled sequence nuclei and on to complete sequence for an intermediate fragment or an entire source DNA molecule. Numerous modifications and variations of the invention could be implemented by one of ordinary skill in the art (column 25, lines 31-37 and column 26).

No claims are allowed.

Inquiries

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and

1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703) 308-4242, or (703) 308-4028.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lori A. Clow, Ph.D., whose telephone number is (703) 306-5439. The examiner can normally be reached on Monday-Friday from 10am to 6:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward, Ph.D., can be reached on (703) 308-4028.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Legal Instrument Examiner, Tina Plunkett, whose telephone number is (703) 305-3524, or to the Technical Center receptionist whose telephone number is (703) 308-0196.

MARJORIE MORAN
PATENT EXAMINER

October 29, 2003
Lori A. Clow, Ph.D.
Art Unit 1631